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- (81) **Designated States** (*unless otherwise indicated, for every kind of national protection available*): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC,

[Continued on next page]

- (54) **Title:** BREATH ANALYSIS SYSTEM

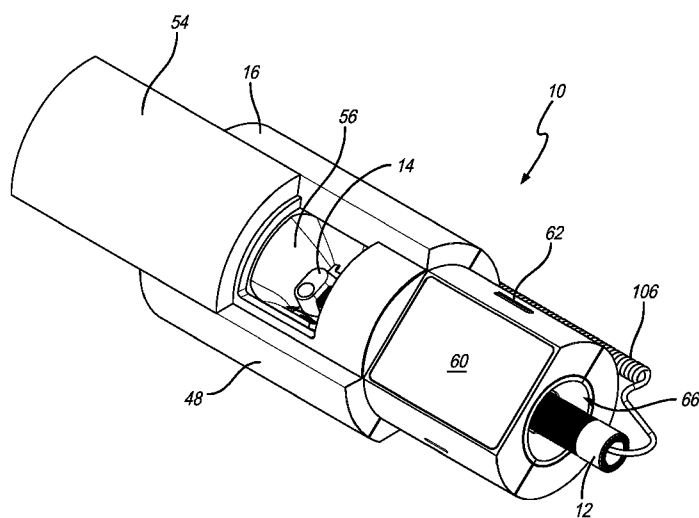


FIG. 1

(57) **Abstract:** A breath analysis system that includes a handle assembly with an analysis cartridge on an upper end thereof. The handle includes a main body portion with a pressure opening and a pressure transducer therein. The analysis cartridge includes a main body portion with an upper portion that defines a breath chamber, a lower portion that defines a fluid chamber and a filter assembly that is movable between a breath capture position and an analysis position. The filter assembly has an opening defined therethrough. In the breath capture position, the opening partially defines the breath chamber and in the analysis position the opening partially defines the fluid chamber. The system also includes an analysis device with door, a controller that controls the motor and a fluorescence detection assembly and a rotation assembly positioned in the case interior. The rotation assembly includes a shroud with a funnel portion for receiving the analysis cartridge.



SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN,
TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA,
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11 August 2016

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 15/38386

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61B 5/097 (2015.01)

CPC - A61B 5/097, A61B 5/082, B01D 46/0001, B01D 46/0002, B01D 46/0023, G01N 2021/0106, G01N 2021/6417

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC(8) - A61B 5/097 (2015.01)

CPC - A61B 5/097, A61B 5/082, B01D 46/0001, B01D 46/0002, B01D 46/0023, G01N 2021/0106, G01N 2021/6417

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

UPC: 600/532, 543, 600/529-543; 422/534-535; 356/300-334 CPC: A61B 5/08*, 5/09*; B01D 46/0023, 0024, 0026; B01D 46/0002, B01D 46/*; G01N 21/62- 21/74, 2021/62- 2021/74 (Search term limited; see below)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

PubWest (PGPB, USPT, EPAB, JPAB); Google; PatBase (All);

Search Terms: Breath, exhal*, sample, collection, captur*, filter*, substrat*, adsor*, rotat*, mov*, displac*, translat*, sensor, measur*, transducer, second, position, condition, state, path, pathway, chemical, reagent, phenylene, diamine, cartridge, ampoule, chamber, valv*,

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2005/0227274 A1 (TAKAHASHI) 13 October 2005 (13.10.2005) Entire document, especially Abstract, para[0051]- para[0056] and FIGS. 1-4.	22-24
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Y		25
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A	US 5,462,061 A (MALOUIER et al.) 31 October 1995 (31.10.1995) Entire document, especially Abstract, col 3, In 12- col 4, In 24 and FIG. 1.	1-21, 26-32
X		33
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A		1-21, 26-32
X	WO 9965383 A1 (TAPUZ MED TECH LTD) 23 December 1999 (23.12.1999) Entire document, especially Abstract, para[0006], para[0011] and FIGS. 1-2.	33-36, 39-40
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Y		37-38
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X	US 4,950,317 A (DOTTERMANS) 21 August 1990 (21.08.1990) Entire document, especially Abstract, col 5, In 4- col 6, In 11 and FIGS. 1-4.	41-43
Y		25
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Y		37-38
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Y	US 2012/0250024 A1 (NODA et al.) 04 October 2012 (04.10.2012) Entire document, especially Abstract, para[0120]- para[0121], para[0128] and FIGS. 1.	41-51
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Y		37-38
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Y	US 4,340,470 A (VAN MOL) 20 July 1982 (20.07.1982) Entire document, especially Abstract, col 2, In 6-31 and FIGS. 1-2.	41-51
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Y		37-38
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☒ Further documents are listed in the continuation of Box C.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

29 October 2015 (29.10.2015)

Date of mailing of the international search report

25 MAR 2016

Name and mailing address of the ISA/US

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 15/38386

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

----- see continuation sheet -----

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☒ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 15/38386

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2002/0189457 A1 (DALLAS et al.) 19 December 2002 (19.12.2002) Entire document, especially Abstract, para[0021]- para[0035], para[0037]- para[0041] and FIG. 2.	41-51
Y	US 2003/0164051 A1 (KUNIMUNE et al.) 04 September 2003 (04.09.2003) Entire document, especially Abstract, para[0026]- para[0027] and FIG. 1.	44, 50
A	US 2008/0056946 A1 (AHMAD) 06 March 2008 (06.03.2008) Entire document, especially Abstract, para[0199]- para[0204] and FIG. 10.	1-21, 26-32
A	US 2014/0081165 A1 (VON BAHR et al.) 20 March 2014 (20.03.2014) Entire document, especially Abstract, para[0028], para[0050]- para[0052] and FIG. 1.	1-21, 26-32
A	US 2004/0149281 A1 (AHLMEN) 05 August 2004 (05.08.2004) Entire document, especially Abstract.	1-21, 26-32
A	US 2011/0006219 A1 (SCHAUSBERGER et al.) 13 January 2011 (13.01.2011) Entire document, especially Abstract, para[0056]- para[0064] and FIGS. 1-2.	1-21, 26-32
A	US 2011/0021942 A1 (CHOE et al.) 27 January 2011 (27.01.2011) Entire document.	1-50
A	US 2010/0241019 A1 (VARGA et al.) 23 September 2010 (23.09.2010) Entire document.	1-50
A	US 7,837,936 B1 (MARTIN) 23 November 2010 (23.11.2010) Entire document.	1-50
A	US 1,927,582 A (DENK) 19 September 1993 (19.09.1993) Entire document.	1-50

----- Continuation of Box III: Observations where unity of invention is lacking (Continuation of item 3 of first sheet) -----

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: claims 1-15, drawn to a breath capture assembly comprising a handle with an analysis cartridge received therein, comprising a upper portion that defines a breath chamber with a breath entry and exit, and a lower portion that defines a fluid chamber, and a filter movable between a first and second position between the breath chamber and lower chamber

Group II: claims 16-32, drawn to a rotation assembly comprising a motor, first and second fixed members, funnel portion, stowed and deployed position, a pivoting arm, shroud and fluorescence detection assembly.

Group III: Claims 33-40 drawn to a handle defining a pressure path

Group IV: Claims 41-51 drawn to a filter assembly and method for making a filter assembly comprising a cylindrical main body defining a first axis, a transversely through opening perpendicular to the first axis, first and second filters spanning the opening and defining a substrate space and a substrate therein

The inventions listed as Groups I - IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Group II shares no features with any other group.

Group III and Group IV share no common features.

Group III shares with Group I, the features of a handle comprising an elongated main body portion that defines a handle interior, a cap disposed at the end of the main body portion that includes a pressure opening defined therein, a pressure transducer disposed in the handle interior. However, said features are known in the art to US 5,462,061 A to Malouvier et al. (hereinafter: Malouvier). Malouvier describes an elongated main body portion that defines a handle interior (handle 10, FIG. 1; col 3, ln 12-31), a cap disposed at the end of the main body portion (top of handle 10, FIG. 1; see col 3, ln 12-31, describing removable) that includes a pressure opening defined therein (note pressure measurement tubes and rings, FIG. 1; col 3, ln 38-50), a pressure transducer disposed in the handle interior (pressure pickup 11, FIG. 1; col 3, ln 38-50)

Group IV shares with Group I, the features of a filter with an opening. However, said features are known in the art to Malouvier who describes a filter with an opening (wire net 8, FIG. 1; col 3, ln 12-65).

Therefore, the groups comprise the unique special features as listed at the top.

Groups I-IV lack unity of invention because they do not share a same or corresponding special technical feature providing a contribution over the prior art.